IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
MARSHALL DIVISION

ECKHARD U. ALT, MD	§	
	§	
Plaintiff	§	
	§	
vs.	§	**CASE NO. 2:04-CV-370**
	§	
MEDTRONIC, INC., a Minnesota Corp.	§	
	§	
Defendant	§	

MEMORANDUM OPINION AND ORDER

Defendant, Medtronic, Inc. ("Medtronic"), has filed a Motion for Leave to Amend its Preliminary Invalidity Contentions (Docket No. 94). For the reasons set forth below, the Court **GRANTS** Medtronic's motion.

BACKGROUND

Dr. Eckhard Alt ("Alt") filed suit against Medtronic on October 15, 2004 alleging infringement of four patents, U.S. Patent Nos. 5,014,700 ("the '4,700 patent"), 5,031,615 ("the '615 patent"), 6,076,014 ("the '014 patent"), and 6,249,700 ("the '9,700 patent"). Pursuant to the Court's Docket Control Order, Alt timely filed his Preliminary Infringement Contentions on February 28, 2005. Similarly, Medtronic timely filed its Preliminary Invalidity Contentions on March 30, 2005 identifying roughly thirty prior art references. On September 23, 2005, Medtronic's counsel sent a letter to Alt's counsel notifying Alt of six additional prior art references discovered by Medtronic relating to the '014 and '9,700 patents:

- U.S. Patent Number 5,193,550: "Method and apparatus for discriminating among normal and pathological tachyarrhythmias." Filed: November 30, 1990: Issued: March 16, 1993;

- Yee, R., et al.; "Initial Clinical Experience with the Pacemaker-Cardioverter-Defibrillator," THE CANADIAN JOURNAL OF CARDIOLOGY, Vol. 6, No. 4,

May 1990;

- Bonnet, C.A., et al., "Long-Term Efficacy of Antitachycardia Pacemaker and Implantable Defibrillator Combination," PACE, Vol. 14, No. 5, Pt. I, May 1991;

- Saksena, S., "The Implantable Cardioverter-Defibrillator: Future Directions," Chapter 48 in IMPLANTABLE CARDIOVERTER-DEFIBRILLATORS: A COMPREHENSIVE TEXTBOOK, (N.A. Mark Estes III, ed., 1994);

- Saksena, S., "New Generations of Implantable Pacemaker Defibrillators for Ventricular and Atrial Tachyarrhythmias," ARCHIVES DES MALADIES DU COEUR ET DES VAISSEAUX, Vol. 89, February 1996; and

- June 30, 1997, Business Wire Press Release, "Guidant announces first implants of VENTAK AV II DR defibrillation system in Europe."

Medtronic's letter stated: "In light of the upcoming deadline for the parties to serve their P.R. 3-6 final contentions, we believe there is no need to amend and/or supplement Medtronic's P.R. 3-3 Preliminary Infringement Contentions with the foregoing information. If you disagree with this approach, please let us know in writing within five (5) days hereof." Additionally, on October 12, 2005, Medtronic's counsel sent Alt's counsel a letter supplementing the September 23, 2005 letter and identifying two additional prior art references:

- U.S. Patent Number 5,792,183: "Combination Pacemaker and Defibrillator Having Dynamic Ventricular Refractory Period." Filed January 27, 1997; Issued: August 11, 1998; and

- U.S. Patent Number 6,128,529: "Device and Method Providing Pacing and Anti-Tachyarrhythmia Therapies." Filed January 29, 1997; Issued: October 3, 2000.

The October 12th letter also indicated that Medtronic did not intend on providing the additional prior art before serving its Final Invalidity Contentions. Alt did not respond in writing to either of Medtronic's letters. On October 21, 2005, Alt's counsel informed Medtronic's counsel that it would object to Medtronic adding the new prior art references in its Final Invalidity Contentions and that Alt would oppose a motion for leave to amend Medtronic's Preliminary Invalidity Contentions.

Medtronic filed its motion on November 11, 2005 requesting leave to amend its Preliminary Invalidity Contentions pursuant to Patent Rule 3-7 to add the eight additional prior art references mentioned above. Alt claims that Medtronic has not shown the requisite good cause necessary to amend its Preliminary Invalidity Contentions.

APPLICABLE LAW

Federal Rule of Civil Procedure 16(b) requires a showing of good cause to modify dates set forth in the Court's scheduling order. Fed. R. Civ. P. 16(b) (providing in part, "a schedule [scheduling order] shall not be modified except upon a showing of good cause and by leave of the district court . . . ."). Patent Rules are considered part of the Court's scheduling order; therefore, a party seeking relief must obtain "the Court's leave on a good cause showing to modify the Patent Rule's deadlines." *STMicroelectronics, Inc. v. Motorola, Inc.*, 307 F. Supp. 2d 845, 849 (E.D. Tex. 2004). "Patent Rule 3-7 incorporates Rule 16(b)'s good cause standard by stating 'amendment or modification of the Preliminary or Final Infringement Contentions or the Preliminary or Final Invalidity Contentions . . . may be made only by order of the Court, which shall be entered only upon a showing of good cause.'" *Id*. (quoting P.R. 3-7). "The 'good cause standard requires the party seeking relief to show that the deadlines cannot reasonably be met despite the diligence of the party needing the extension.'" *Id*. at 850 (quoting *S & W Enters., L.L.C. v. Southtrust Bank of Ala., NA*, 315 F.3d 533, 535 (5th Cir. 2003)). A trial court has broad discretion in allowing scheduling order modifications. *Id*. The Court should consider four factors when determining whether to allow a scheduling order modification: (1) the explanation for the failure to meet the deadline; (2) the importance of the thing that would be excluded; (3) potential prejudice in allowing the thing that would be excluded; and (4) the availability of a continuance to cure such prejudice. *Id*. (citing *S & W Enter., L.L.C.*, 315 F.3d at 535-36).

ANALYSIS

Medtronic's Explanation for Its Failure to Meet the Deadline

Medtronic argues that its inability to identify the additional prior art references before filing its Preliminary Invalidity Contentions was not unreasonable. Medtronic claims that it only had five months from the date the suit was filed and one month from the date Alt filed its Preliminary Infringement Contentions to identify prior art to include in its Preliminary Invalidity Contentions. Medtronic argues that Alt's infringement claims were very broad and unclear during the first four months of the lawsuit and that it was not until Medtronic received Alt's Amended Preliminary Infringement Contentions, *Markman* briefing, and Technology Tutorials in June through August of 2005 that Medtronic could confidently focus its prior art searches to only those devices using accelerometer-based activity sensors. Alt argues that the accelerometer has clearly been at issue from the beginning of the case in that claim two of the '4,700 patent indicates that the detecting means includes an "accelerometer." Alt also contends that accelerometer-based products have clearly been at issue throughout Alt's history of trying "to get paid" for his inventions. Medtronic responds that Alt's interpretation of accelerometer was much broader early in the case and included devices that measured vibrations. Medtronic's piezoelectric crystal activity sensor measures vibrations and is found in many of its devices. Consequently, more of Medtronic's pacemaker and defibrillator products were at issue in the case. Medtronic claims that it was not until June 12, 2005 that Alt eliminated Medtronic's devices with piezoelectric crystal activity sensors from the accused products in the case. Furthermore, Medtronic argues that Alt initially identified the corresponding structure of "means for detecting movements" as "activity sensor 3 or its equivalent" before narrowing its focus to "accelerometer" in its Opening *Markman* Brief filed on July 29, 2005.

Furthermore, Medtronic claims it did not learn that Alt intended to rely on a conception date

that pre-dated the effective filing dates for all of the patents-in-suit until April 6, 2005. Medtronic contends that this change required it to expand its prior art searches by nearly four years in the case of the '014 patent, whose filing date is August 1, 1997 and claimed invention date is October 7, 1993. Medtronic claims learning of the 1993 conception date required it to broaden its research to find prior art references that predated the 1993 conception date as opposed to a 1997 conception date. Alt claims that even if Medtronic was unaware of the 1993 conception date during its early searching, it had no effect on the range of years Medtronic searched. Alt also argues that Medtronic was not disadvantaged by not knowing Alt's alleged conception date in searching for prior art because "the earlier, the better" as far as prior art is concerned. Medtronic argues that prior art closely related in time to the conception date is usually the most similar and, therefore, the most relevant as it applies to invalidity.

Medtronic claims to have diligently collected and read books and articles on cardiac pacing and arrhythmia treatment and detection before turning certain articles over to its invalidity experts in August and September of 2005. The four articles referenced in the September 23, 2005 letter above are the product of this process. Alt argues that Medtronic was not diligent in researching articles and had previous insight into Alt's infringement claims. Alt basis this conclusion on the fact that Medtronic admits that its own in-house counsel investigated the asserted patent claims in 1999 and 2003 and in some cases as far back as 1990. Medtronic points out that the in-house analysis Alt refers to related to infringement and did not concentrate on invalidity issues related to Alt's patents. Medtronic claims it did not have a reason to research prior art until the present suit was filed.

Medtronic also claims it continued to interview current and former Medtronic employees with possible knowledge of facts relevant to the lawsuit after filing its Preliminary Invalidity

Contentions. In September 2005, while interviewing Ed Duffin, a Medtronic Employee, Medtronic learned that Cardiac Pacemakers, Inc. ("CPI") had released a rate responsive implantable cardioverter defibrillator ("ICD") called the Ventak AV II DR. Upon further research, Medtronic's counsel discovered a press release indicating that the Ventak device used an accelerometer as its activity sensor. Consequently, Medtronic discovered two Ventak-related patents, U.S. Patent Nos. 5,792,183 and 6,128,529. Medtronic then concluded that the Ventak patents and device were potential prior art to both the '014 and '9,700 patents-in-suit. Additionally, Medtronic's interviews with Mr. Duffin led it to conclude that U.S. Patent No. 5,193,550 ("the '550 patent"), a Medtronic patent, was also potential prior art to '014 and '9,700 patents-in-suit.

Alt claims that Medtronic's was not diligent in asking for information from its own employees once the suit was filed, evidenced by the fact that Medtronic waited until September to interview "Medtronic technical people." Alt claims that the Ventak product should not have been a "new discovery" to Medtronic because the product was made by one of Medtronic's direct competitors and was first used in Europe in 1997. Medtronic responds that its delay in discovering the Ventak product and patents was due to Alt's failure to identify the Ventak products in answers to interrogatories requesting information on all licensees using Alt's patents and prior infringement assertions relating to the patents-in-suit.

Medtronic has shown that it was diligent in its attempts to discover relevant prior art before and after the filing of its Preliminary Invalidity Contentions. Alt apparently had a broader definition of activity sensor at the beginning of the case, which directed Medtronic's research to a larger spectrum of devices than are presently at issue in the case. Medtronic's discovery of more relevant prior art after narrowing a key issue in this complex and document intensive case is not surprising.

Alt's argument that Medtronic's prior art search related to the '014 patent was not effected by its delayed knowledge of the 1993 conception date is not persuasive. Upon learning of Alt's 1993 conception date, Medtronic needed to find prior art predating the 1993 conception date. The closer in time prior art is to the conception date the more relevant the prior art is likely to be in terms of invalidity. In complex litigation such as the present case, each party relies heavily on the discovery responses of the opposing party to help guide future research. A party that fails to disclose information in a discovery response has little room to complain of the requesting party's timeliness when the requesting party later discovers the same information through the requesting party's own research. Thus, it appears Alt hindered Medtronic's ability to meet the March 30 deadline. Furthermore, the fact that Ventak was made by a competitor of Medtronic does not ensure that Medtronic actually had knowledge of the product prior to this lawsuit. In the context of the circumstances described above, it is not unreasonable that Medtronic could not meet the March 30, 2005 Preliminary Invalidity Contentions deadline with regards to the additional prior art references.

The Importance of the Additional Prior Art References

Medtronic argues that the Ventak patents and press release are particularly important to this case in that they show a prior invention of an ICD using an accelerometer by someone other than the alleged inventor, as well as prior knowledge of such a product within the United States. Both of these determinations could potentially have a strong impact on Alt's claims related to accelerometer-based devices. Medtronic claims that the '550 patent is important in that it evidences Medtronic's independent and earlier invention of the technology that Alt claims in the '014 and '9,700 patents. Such evidence supports Medtronic's claim that it was not knowingly and willfully infringing by copying Alt's technology. Finally, Medtronic claims that the four articles demonstrate that rate-

responsive capabilities in an ICD were known to the medical world before Alt's alleged invention. Medtronic contends that these prior art references are very important to its ability to mount a defense to Alt's infringement claims and that Medtronic would suffer significant prejudice in the event it was not allowed to present these references. The Court is persuaded by Medtronic's arguments.

The Potential Prejudice to Alt in Allowing the Additional Prior Art References

Medtronic claims that Alt would not suffer any potential prejudice by the addition of the eight prior art references. Medtronic argues that Alt had notice of Medtronic's intentions to claim invalidity of its patents and of the additional prior art references since September 23 and October 12, 2005. Alt argues that he will be prejudiced by not being able to account for these references in his claim construction briefing and *Markman* arguments. Alt relies on language from the Court's Order of October 28, 2005 denying Alt's motion to amend its infringement contentions that states, "Considering that the claim construction briefing and the *Markman* hearing have already concluded, a continuance is not likely to remedy any potential prejudice that [the party opposing the motion to amend] might suffer." The present situation is distinguishable from that addressed by the Court in Alt's motion to amend its Preliminary Infringement Contentions. In Alt's motion, he requested leave to amend his Preliminary Infringement Contentions to add a new claim. The addition of prior art references post *Markman* do not have the same implications upon *Markman* briefing and arguments as the addition of a patent claim. Alt's position requires a *per se* rule that invalidity contentions cannot be amended after *Markman*. The Court is unwilling to adopt such a rule. Furthermore, Alt does not identify any particular arguments or additional claims that he would have asserted in response to the additional prior art references.

Alt also claims that he will be prejudiced because Medtronic has not yet disclosed its Rule

3-3 analysis of the prior art references and the initial expert report deadline was December 30, 2005 with a discovery deadline of February 10, 2006. Expert witness reports are now due on January 31, 2006 and the discovery deadline is now February 28, 2006. There is a potential that Alt could suffer prejudice in regards to these dates at this point in time. However, the fact that Alt has been aware of Medtronic's intent to add the additional prior art references since at least October 12 diminishes the likelihood that he would suffer prejudice. Alt had the opportunity to inform Medtronic that he objected to the addition of the prior art references in response to the letters sent by Medtronic in September and October of 2005. Alt did not take this opportunity. Alt chose to lay behind the log, and the Court does not consider Alt blameless for any prejudice he might suffer from the addition of the references. Additionally, any prejudice that Alt might suffer could be cured by a continuance, as discussed below.

Availability of a Continuance to Cure Such Prejudice

The Court is not convinced that Alt will suffer prejudice as a result of Medtronic's amending its Preliminary Invalidity Contentions. However, in the event that Alt does suffer any prejudice, it would likely arise in connection with the discovery deadline or Alt's ability to prepare expert witness reports. If the Court finds that Alt suffers such prejudice, it can easily be cured with an appropriate continuance of these deadlines.

CONCLUSION

Medtronic has met the good cause standard required to amend its Preliminary Invalidity Contentions to add the eight additional prior art references listed above. Accordingly, the Court **GRANTS** Medtronic's Motion for Leave to Amend its Preliminary Invalidity Contentions.

So ORDERED and SIGNED this 1st day of February, 2006.

LEONARD DAVIS
UNITED STATES DISTRICT JUDGE